No. 12,483

IN THE

United States Court of Appeals

For the Ninth Circuit

ALBERTY FOOD PRODUCTS CO., a copartnership consisting of ADA J. ALBERTY, HARRY R. ALBERTY, HELEN M. ALBERTY HACKWORTH, KENNETH J. HACKWORTH, FLORENCE M. ALBERTY ST. CLAIR and MARGARET M. ALBERTY QUINN,

Appellant,

vs.

UNITED STATES OF AMERICA,

Appellee.

Appeal from the United States District Court, Northern District of California, Southern Division.

BRIEF FOR APPELLEE.

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BRIEF FOR APPELLEE.

I.

STATEMENT OF JURISDICTION.

Under 21 U.S.C. 334(a) and (f), the District Court had jurisdiction over the libel for condemnation proceedings involved in this appeal.

Under 28 U.S.C. 1291, this Court has jurisdiction to review the decision of the District Court provided, of

course, the appeal satisfies the fundamental requirement that it be a "case" or "controversy" within the meaning of Article 3, Section 2, of the Constitution. We believe this appeal has become moot and that this Court is without jurisdiction to entertain this appeal.

On April 3, 1950, this Court denied our motion to dismiss the appeal without prejudice to its renewal on the hearing of the cause on its merits. It is our intention to renew the motion to dismiss at the hearing. We will discuss the pertinent authorities in this brief in the part containing our argument.

II.

STATEMENT OF THE FACTS.

This case arose in the District Court of the United States for the District of Colorado, as a libel for condemnation proceeding under the Federal Food, Drug, and Cosmetic Act. [21 U.S.C. 334(a)]. By order of that Court, the case was removed to the District Court of the United States for the Northern District of California, Southern Division. (R. 11).

The libel filed by the Government charges that the drug involved, Ri-Co Tablets, was misbranded in violation of 21 U.S.C. 352(f)(1) in that its labeling failed to bear adequate directions for use since it did not state the purpose or condition for which the drug was intended. (R. 3).

The only directions contained in the labeling of the drug read as follows (R. 57):

"Three tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed."

There was no statement in the labeling regarding the purpose or condition for which the drug was intended. Newspaper advertisements in the record, however, show that the drug was intended for use in the treatment, mitigation, and cure of arthritis and rheumatism. (R. 58 and 59).

On May 15, 1947, Alberty (the claimant) filed exceptions to libel. (R. 16). Essentially, these exceptions asserted that the Federal Food, Drug, and Cosmetic Act does not require the labeling of a drug to state the disease conditions for which the drug is to be used. Consequently, the exceptions challenged the sufficiency of the libel to state a cause of action.

On September 30, 1947, Judge Harris overruled the exceptions. (R. 18).

On December 1, 1947, Alberty filed an answer to the libel admitting that the Ri-Co Tablets then under seizure were a drug that had been shipped interstate. (R. 18-19).

On October 15, 1948, the Government filed a motion for summary judgment asserting that (1) there were no facts in dispute, and (2) the only legal issue had been decided in favor of the Government when the District Court overruled claimant's exceptions to libel. (R. 21).

In support of the motion for summary judgment, the Government filed an affidavit of a food and drug

representative incorporating the complete labeling of Ri-Co Tablets and two newspaper advertisements of Ri-Co Tablets. (R. 54-59). The Government also filed affidavits from prominent physicians attesting to the worthlessness of Ri-Co Tablets in the treatment or cure of arthritis or rheumatism. (R. 61-70).

Alberty filed no counter-affidavits.

On November 16, 1949, after a full hearing, the District Court granted the motion for summary judgment. The Court's considered oral opinion appears in the record on pages 43-53. The Court's findings of fact and conclusions of law appear in the record on pages 24-31. The Court's decree of condemnation and destruction is in the record on pages 32-33.

Pursuant to the writ of destruction issued by the District Court, no stay of execution having been obtained by Alberty, the United States Marshal destroyed the Ri-Co Tablets under seizure on December 14, 1949. (R. 35-37). On December 16, 1949, Alberty filed a notice of appeal. (R. 34).

III.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED.

Constitution

Article 3, Section 2

> "The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Au-

thority; * * * to all Cases of admiralty and maritime Jurisdiction; to Controversies to which the United States shall be a Party * * *"

Federal Food, Drug, and Cosmetic Act

"Section 201. *Definitions; generally* [21 U.S.C. 321]

For the purpose of this chapter—

(g) The term 'drug' means * * * (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals * * *

(m) The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

"Section 304. *Seizure—Grounds and jurisdiction* [21 U.S.C. 334]

(a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as

nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury * * *"

"Section 502. *Misbranded drugs and devices.* [21 U.S.C. 352]

A drug or device shall be deemed to be misbranded—

(f) Unless its labeling bears (1) adequate directions for use * * *"

IV.

QUESTIONS INVOLVED.

Two questions relate to jurisdiction:

(1) Since the *res* in the instant proceeding has been destroyed, is this Court without jurisdiction to entertain this appeal?

(2) If this Court is without jurisdiction to entertain this appeal, should the appeal be dismissed?

If this Court does have jurisdiction, four additional questions are presented:

(3) Did the District Court err in holding that the civil rules rather than the admiralty rules govern libel for condemnation proceedings under 21 U.S.C. 334 after seizure of the allegedly offending article has been accomplished?

(4) Did the District Court err in applying the summary judgment procedure provided by Rule 56 of the Federal Rules of Civil Procedure?

(5) Was there any genuine issue of fact before the District Court?

(6) To comply with the statutory requirement that the labeling of a drug must bear adequate directions for use, is it necessary, as a matter of law, that the labeling include a statement of the diseases or conditions of the body for which the drug is offered to the public by the claimant?

V.

SUMMARY OF ARGUMENT.

A. This Court is without jurisdiction to entertain this appeal and should grant the Government's motion to dismiss.

This is an *in rem* proceeding where the continued existence of the *res* is an indispensable jurisdictional element.

The District Court ordered the Ri-Co Tablets here involved to be condemned and destroyed.

Appellant failed to obtain a stay of execution of the lower Court's judgment, and the Tablets were destroyed by the U. S. Marshal pursuant to the judgment.

With the Tablets destroyed, this proceeding has become moot and is no longer a "case" or "controversy" within the meaning of Article 3, Section 2 of the Constitution.

Where a case becomes moot on appeal through no fault of the appellant, the Appellate Court may reverse and order the suit dismissed if the ends of

justice so dictate. Here, the appeal has become moot because of the appellant's negligence. Moreover, appellant has a long history of adjudicated violations of the Federal Food, Drug, and Cosmetic Act. Consequently, there is no valid basis for putting a premium upon appellant's negligence by reversing the District Court.

The appeal should be dismissed and the judgment of the District Court should be permitted to stand.

The rest of the argument is pertinent only if this Court has jurisdiction to hear the appeal.

B. The District Court did not err in holding that the Civil Rules rather than the Admiralty Rules governed this proceeding after seizure of the res was effected.

Seizure actions under the Federal Food, Drug, and Cosmetic Act are civil in nature but by statute they conform to the admiralty procedure "as nearly as may be".

A similar provision in the predecessor law was held by the Supreme Court to mean that the admiralty rules ceased to apply beyond seizure of the property, and that thereafter the civil rules governed.

While the Courts have not been unanimous in construing the new law, the majority and better rule is that the civil rules apply once the property has been seized.

C. The District Court did not err in holding that there was no genuine issue as to any material fact, and in ruling that the labeling of a drug must state the diseases or conditions of the body for which it is offered to the public.

Ri-Co Tablets are offered to the public by Alberty for use in the treatment and cure of arthritis and rheumatism.

It is admitted that the Tablets here involved were drugs, that they moved in interstate commerce, and that their labeling did not state any disease or condition for which they were to be taken.

The only question before the District Court was whether the labeling of this drug failed to bear "adequate directions for use" in violation of 21 U.S.C. 352(f)(1).

As a matter of law, it is settled that the labeling of a drug cannot bear adequate directions for use unless it states the disease or conditions of the body for which the drug is offered to the public.

This works no hardship on honest enterprise but merely requires the unscrupulous vendor of worthless panaceas to come out in the open with his therapeutic claims.

The Government is not here seeking to regulate advertising, but is exacting full compliance with the labeling requirements of the Federal Food, Drug and Cosmetic Act.

There was no genuine issue of fact before the District Court.

D. The summary judgment procedure authorized by Civil Rule 56 was properly invoked by the District Court.

Civil Rule 56 is applicable to all civil actions.

The summary judgment procedure is an inquiry in advance of trial to determine whether there is a genuine issue of fact. Its purpose is to avoid the necessity of a futile trial where there is no genuine issue of fact.

If it appears from the pleadings and affidavits that there is no genuine issue as to any material fact and that the issue is one of law, then if the law so warrants a summary judgment should be entered.

The record before the District Court shows that there was no genuine issue of fact. Since the law warranted the entry of a summary judgment, the District Court properly invoked Civil Rule 56.

E. Conclusion.

The Court is without jurisdiction to entertain this appeal since the case has become moot by reason of the destruction of the *res*. The appeal should be dismissed without impairing the validity of the judgment of the District Court.

If this Court does have jurisdiction to consider the appeal, the judgment of the District Court should be affirmed in all respects.

VI.

ARGUMENT.

This appeal is but one small though important segment in almost two decades of litigation involving appellant's violations of the Federal food and drug laws. We feel it desirable that the Court see this case in its proper perspective in order to evaluate the arguments and objectives of the parties. Therefore we shall briefly sketch in the background of this case.

Ada J. Alberty, and the various firms through which she has operated, have long been doing an extensive interstate business in a number of articles consisting for the most part of dried plants, cereals, vitamins, minerals, and chemicals in various combinations.

Consistently, Mrs. Alberty has sold her products on the basis of false and misleading therapeutic claims ranging from restoration of original color to gray hair to restoration of lost manhood. For every affliction or aberration of mankind, physical or mental, she has a remedy that is represented to prevent or cure it.

In the enforcement of the Federal food and drug laws, dozens of Mrs. Alberty's products have been seized and condemned in various judicial districts. See, for example, Drugs and Devices Notice of Judgment Nos. 829 and 2057, of which the Court may take judicial notice. *Colgrove v. U. S.,* 176 F. (2d) 614, 615 footnote 1 (C.A. 9, 1949), cert. denied 338 U.S. 911 (January 9, 1950).

At first, Mrs. Alberty's therapeutic claims for her drugs were made in labeling that was either affixed

to the drug containers or physically accompanied the drugs in their interstate movement. This permitted the Government to make the direct charge that the labeling was false and misleading in violation of 21 U.S.C. 352(a). In every such instance, where the merits of Mrs. Alberty's products were directly in issue, the Government has prevailed:

(a) In 1936, after a full trial, she was convicted in the Southern District of California on 10 Counts of a criminal information and sentenced to pay a fine of $1000 and costs of almost $1500. That conviction was upheld by this Court on appeal. *Alberty v. U. S.*, 91 F. (2d) 461 (C.A. 9, 1937).

(b) In 1937, she was convicted in the Southern District of California on a plea of *nolo contendere* to a criminal informtion and fined $150. Notice of Judgment, F.D., 28688.

(c) In 1942, after a full trial, 10 of her products were condemned and ordered destroyed by the U. S. District Court for the Northern District of California. Drugs and Devices Notice of Judgment No. 829.

Thereafter, Mrs. Alberty's promotional methods became more sophisticated. Instead of shipping her false and misleading literature interstate together with the drugs to which it related, she shipped the literature separately from the drugs and at different times. This did not impair her sales since she shipped the literature and the drugs to retail stores who displayed them together to the ultimate purchasers.

Upon such facts, the Government filed another criminal information in the Southern District of California. By stipulation, it was admitted that the claims made in the literature were false and misleading. The only question presented to the Court was whether the literature, which was shipped interstate 71 days before the drug, constituted "labeling" within the meaning of the Act. The District Court held that it did. *U. S. v. Alberty,* 65 F. Supp. 945 (S.D. Calif., 1946). However, this Court reversed, pointing out defects in the criminal information. *Alberty v. U. S.,* 159 F. (2d) 278 (C.A. 9, 1947).

It is now settled that where literature and drugs are shipped interstate as parts of an integrated distribution program, the literature accompanies the drugs and constitutes labeling even though shipped separately and at a different time from the drug. *Kordel v. U. S.,* 335 U.S. 345 (1948); *U. S. v. Urbuteit,* 335 U.S. 355 (1948).

The *Kordel* and the *Urbuteit* cases served merely as a challenge to Mrs. Alberty. To circumvent them, she resorted to several techniques, in some instances such as the present one actually anticipating the Supreme Court's ruling. Thus she shipped the Ri-Co Tablets interstate without making any therapeutic claims in her labeling. Sales promotion was achieved through therapeutic claims made in newspaper advertising. (R. 58). The identical situation also appears in a seizure action pending in the U. S. District Court for the District of Columbia. *U. S. v.*

Various Quantities . . . "Instant Alberty Food", 83 F. Supp. 882, 885 (1949).

Obviously, Mrs. Alberty's theory is that since her therapeutic claims are false and misleading, and cause her drugs to be misbranded when the claims appear in the labeling, she can avoid violation of the law merely by eliminating the claims from the labeling. However, in both the instant case and the District of Columbia case, the District Courts have held that her drugs are misbranded if their labeling does not state every ailment of the body for which they are actually held out to the public.

Even while these cases are pending, Mrs. Alberty has developed other sales-promotion techniques. From retail stores throughout the country, she has obtained large mailing lists of persons who are susceptible to the type of merchandise she vends. She now mails interstate vast quantities of false and misleading literature direct to those persons, and stamps on such literature the name and address of the retail store, in the vicinity of the addressee, where her drugs can be bought.

In a final effort to deal with this situation at its source, the Government has filed a Complaint for Injunction against Mrs. Alberty and her firm in the Southern District of California (No. 10,322-WM Civil). The Complaint involves 29 drugs. One of the issues in that proceeding is whether the literature, as she now ships it, constitutes the labeling of the

drugs to which it relates. That case is set for trial on September 19, 1950.

Actually, we have spoken only of litigation under the Federal Food and Drugs Act of 1906 and the Federal Food, Drug, and Cosmetic Act of 1938. In addition, Mrs. Alberty has been involved in considerable litigation under the Federal Trade Commission Act. See, for example, *Ada Alberty v. Federal Trade Commission,* 118 F. (2d) 669 (C.A. 9, 1941), cert. denied 214 U.S. 630; *Ada J. Alberty v. Federal Trade Commission,* 182 F. (2d) 36 (C.A.D.C., 1950).

We turn now to the specific issues before this Court.

A. THIS COURT IS WITHOUT JURISDICTION TO ENTERTAIN THIS APPEAL AND SHOULD GRANT THE GOVERNMENT'S MOTION TO DISMISS.

All in all, the United States Marshal seized 8 bottles of Ri-Co Tablets pursuant to the process that issued upon the filing of the Libel in this cause. (R. 8). Since the retail price per bottle is two dollars, the total value was $16.

Pursuant to the Writ of Destruction issued by the District Court on November 29, 1949, the United States Marshal destroyed the 8 bottles of Ri-Co Tablets on December 14, 1949. (R. 35-37). This was done in compliance with Rule 62(a) of the Federal Rules of Civil Procedure. Consequently, the *res* which was the subject of this action is no longer in existence.

This case arose as a seizure action under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 334(a)]. Such suits are directed against the offending articles themselves and are deemed to be *in rem* proceedings. *United States v. 935 Cases . . . Tomato Puree,* 136 F. (2d) 523, 525 (C.A. 6, 1943), cert. denied 320 U.S. 778.

Since the decree of condemnation of the District Court provided for the destruction of said Ri-Co Tablets, and inasmuch as the decree has been executed by their destruction, we submit that the proceedings are at an end.

The identical situation was involved in *United States v. 3 Unlabeled 25-Pound Bags Dried Mushrooms,* 157 F. (2d) 722 (C.A. 7, 1946), where condemnation proceedings under the Federal Food, Drug, and Cosmetic Act had been instituted against mushrooms alleged to be adulterated. After trial, a decree of condemnation and destruction was entered. An appeal was taken to the Court of Appeals, but since no stay of the decree had been obtained by the claimant of the product, the Marshal destroyed the mushrooms. In dismissing the appeal as moot, the Court of Appeals, per Minton, J., said at page 723:

> "The continued existence of the mushrooms is essential to our right to proceed against the things themselves. The action is an action in rem. In such a proceeding, there is no party defendant. The goods stand to answer. They are the offenders. Day v. Micou, 85 U.S. 156, 162, 21 L. Ed. 860; National Bond & Investment Co. v. Gibson, D. C., 6 F. (2d) 288, 290.

"The decree of the District Court goes against the mushrooms. The decree having been entered and executed, the proceeding is functus officio.

"Counsel for the Government readily admits the matter is moot here and counsel for the claimant reluctantly admits it is moot, but both parties ask us to decide the issue between them. This we decline to do. If we were to affirm the judgment, the District Court could not destroy the mushrooms. They have already been destroyed. If we reversed the judgment, there would be no mushrooms to restore to the claimant. The cause is clearly moot. We are not authorized to decide arguments but only 'cases and controversies'."

A closely analogous situation arose in *Eureka Productions, Inc. v. Mulligan,* 108 F. (2d) 760 (C.A. 2, 1940). There Eureka had imported a motion picture film into the United States. The Collector of Customs seized it on the ground that it was obscene. The Government then filed a libel in the District Court, charging that the film was obscene and asking for its destruction. Eureka intervened as claimant, and the case was tried before a jury which returned a verdict that the film was obscene. The District Court then entered a judgment ordering that the film be forfeited and destroyed.

Eureka filed a notice of appeal but did not get an order staying execution of the writ of destruction. Several days later, Mulligan, the U. S. Marshal, destroyed the film in obedience to the writ of destruction. The appeal was later dismissed in the Court of

Appeals for the Second Circuit on the ground that the film had already been destroyed.

Thereafter, Eureka sued Mulligan for damages contending that the case was in admiralty and that the mere filing of an appeal suspended execution of the decree.

The Court of Appeals held that the condemnation suit was an action at law, and affirmed the District Court in dismissing the damage suit. At page 761, the Court made some remarks that are relevant to Alberty's contention in the instant case that the present proceeding is governed entirely by the admiralty rules:

> "* * * In the case of seizures on land, suit for condemnation of the thing seized, though brought in the form of a libel of information in admiralty and governed to some extent by Admiralty Rule 22 * * *, is inevitably an action at law. The Sarah, 8 Wheat. 391, 5 L. Ed. 644; Morris's Cotton, 8 Wall. 507, 19 L. Ed. 481; Confiscation Cases, 20 Wall. 92, 22 L. Ed. 320. * * * The resemblance to a suit in admiralty does not go beyond the process and the initial pleadings, even in cases where the statute providing for confiscation directs that the proceedings shall conform to proceedings in admiralty as near as may be. In re Graham, 10 Wall. 541, 19 L. Ed. 981; 443 Cans of Frozen Egg Product v. United States, 226 U.S. 172, 33 S. Ct. 50, 57 L. Ed. 174."

It is clear, therefore, since the subject matter of the instant litigation has been destroyed, that the

cause is moot and no case or controversy exists under Article 3, Section 2, of the Constitution. See *United States v. Hamburg-Amerikanische Packetfahrt-Actien Gesellschaft,* 239 U.S. 466, 475-476; *St. Pierre v. United States,* 319 U.S. 41. Cf. *Fiswick v. United States,* 329 U.S. 211, 220-223.

Despite these principles, counsel for Alberty argued, in opposition to the original Motion to Dismiss the appeal, that this Court should determine the merits of the case because of the alleged effect that the District Court judgment would have on Alberty. The contention was that if the appeal is dismissed and the judgment of the District Court permitted to stand, the government could institute multiple seizures of Ri-Co Tablets all over the country pursuant to 21 U.S.C. 334(a). Moreover, through the operation of *res judicata,* claimant would be deprived of an opportunity to defend. We suggest that this argument is without substance.

Claimant appears to be saying this: That it will be seriously prejudiced by the failure of this Court to review the merits of the case. But the mere fact that the claimant has placed himself in a position which may result in prejudice to him does not confer jurisdiction on a court. In an ordinary case, a party who fails to appeal within the prescribed time cannot be heard to complain, in a subsequent suit, that the merits of his case were never passed on by an appellate tribunal and that therefore the lower Court judgment should be given no effect. We see no difference between that situation and the one at bar.

appeal. *This appeal became moot, not by an act of God or a war, but by Alberty's negligence in failing to obtain a stay of execution of the judgment.* At the oral argument on the Motion to Dismiss, this Court observed that an appellant has a duty to protect his right of appeal. As a corollary to that, we urge that appellant should not be given an opportunity to snatch victory from defeat *as a result of its own negligence* in perfecting its appeal.

There can be no argument that the equitable principles enunciated by the Supreme Court in the *Hamburg* case are most commendable. We think likewise that those principles should be applied to serve the ends of justice, and to promote respect rather than disdain for the law. Alberty's objective is to circumvent the Federal Food, Drug, and Cosmetic Act by constant probing for loopholes in technicalities. If this Court should declare the appeal moot but reverse the judgment of the District Court, Alberty would feel that this Court had helped her to "get around" the law.

For the foregoing reasons, we respectfully submit that this appeal is moot and should be dismissed, and that the judgment of the District Court should be permitted to stand.

The remainder of this brief is pertinent only if the Court decides it has jurisdiction to hear this appeal on its merits.

B. THE DISTRICT COURT DID NOT ERR IN HOLDING THAT THE CIVIL RULES RATHER THAN THE ADMIRALTY RULES GOVERNED THIS PROCEEDING AFTER SEIZURE OF THE RES WAS EFFECTED.

The pertinent statutory provision, 21 U.S.C. 334(b), reads:

> "The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury * * *"

This provision is a part of the Federal Food, Drug, and Cosmetic Act enacted in 1938.

The predecessor law repealed by the Act of 1938 was the Federal Food and Drugs Act of 1906. It contained a provision almost identical with the above-quoted section.

> 21 *U.S.C.A.* 14 (34 Stat. 771)
> "* * * The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any such case. * * *"

This provision was construed by the Supreme Court in *443 Cans of Frozen Egg Product v. United States,* 226 U.S. 172 (1912). In that case, the Government filed a libel alleging that the Frozen Egg Product was adulterated. After a trial without a jury, the District Court dismissed the libel.

The Government appealed to the Court of Appeals contending that the admiralty rules were applicable and that it was therefore entitled to a review *de novo*. The Court of Appeals reviewed the case upon the facts, reversed the judgment of the District Court, and entered a decree of condemnation. [193 Fed. 589].

The Supreme Court reversed, stating on page 183:

> "We do not think it was intended to liken the proceedings to those in admiralty beyond the seizure of the property by process *in rem,* then giving the case the character of a law action, with trial by jury if demanded and with the review already obtaining in actions at law."

It will be noted that the narrow question before the Supreme Court was whether the admiralty or the civil rules govern these cases *on appeal,* though the ruling of the Court is broader in scope since it indicates the admiralty rules are not applicable after seizure of the property.

With the enactment of the Federal Food, Drug, and Cosmetic Act of 1938, and the concomitant adoption of the Federal Rules of Civil Procedure, there was some uncertainty regarding the point at which the admiralty rules ceased to be applicable. Thus in the early years of enforcement of the Act of 1938, several cases held that the admiralty rules apply even after seizure of the property. On page 10 of its opening brief, Appellant cites two of these cases, *U.S. v. 149 Gift Packages, etc.,* 52 F. Supp. 993 (E.D.N.Y.,

1943), and *U.S. v. 720 Bottles . . . Vanilla Extract,* 3 F.R.D. 466 (E.D.N.Y., 1944). An analysis of these cases reveals that the results would probably have been the same had the civil rules been held to apply.

However, there is now an imposing group of authorities in support of the proposition that the civil rules apply in these seizure actions as soon as the property proceeded against has been seized.

U.S. v. 88 Cases . . . Birely's Orange Beverage, 5 F.R.D. 503 (D.N.J., 1946);

U.S. v. 300 Cans . . . Black Raspberries, et al., 7 F.R.D. 36 (N.D. Ohio, 1946);

U.S. v. 935 Cases . . . Tomato Puree, 136 F. (2d) 523, 525 (C.A. 6, 1943), cert. den. 320 U.S. 778;

U.S. v. 20 Cases . . . Jell-O, 77 F. Supp. 231 (S.D.N.Y., 1947).

See also

Eureka Productions, Inc. v. Mulligan, 108 F. (2d) 760, 761 (C.A. 2, 1940);

C.C. Co. v. U.S., 147 F. (2d) 820, 824 (C.A. 5, 1945).

As the Court said recently in *United States v. 5 Cases . . . Figlia Mia Brand,* 179 F. (2d) 519 (C.A.2, 1950):

> "It now appears well-established that the Rules of Civil Procedure do apply to condemnation proceedings."

In view of these developments, the Government has abandoned its earlier position that the admiralty rules

apply in seizure actions beyond apprehension of the property. For some time now, the discovery procedure authorized by the Federal Rules of Civil Procedure has been regularly invoked in seizure actions by claimants and by the Government. Likewise, the Government has sought and obtained summary judgments under Civil Rule 56(a) in such cases. (R. 45). Such procedure is available to claimants also.

In summary, it is clear from the authorities that these seizure actions are basically civil in nature. The admiralty procedure is adopted for the limited purpose of utilizing an established method of apprehending property in an *in rem* proceeding. Beyond apprehension of the property, there is no reason in logic why the admiralty rules should apply. The trial in such a case may be with or without a jury, as the claimant elects. [21 U.S.C. 334(b)]. Where trial is by jury, then the civil rules must perforce apply since the admiralty rules do not contemplate jury trials. To say that the admiralty rules apply where a jury is waived is to declare that the same type of proceeding may be governed by admiralty or civil rules depending upon the wishes of the claimant. It should be noted that in the instant case, Alberty demanded a jury trial. (R. 20).

We submit that the District Court did not err in holding that the civil rules governed this case after the apprehension of the Ri-Co Tablets.

C. THE DISTRICT COURT DID NOT ERR IN HOLDING THAT THERE WAS NO GENUINE ISSUE AS TO ANY MATERIAL FACT, AND IN RULING THAT THE LABELING OF A DRUG MUST STATE THE DISEASES OR CONDITIONS OF THE BODY FOR WHICH IT IS OFFERED TO THE PUBLIC.

From the pleadings (R. 2-4, and 18-19) and from the labeling of the Ri-Co Tablets involved (R. 57), three significant facts stand out as admitted:

(1) These Tablets were drugs.

(2) They moved in interstate commerce.

(3) Their labeling did not state any disease or condition for which the tablets were to be taken.

If any question remained whether these tablets were drugs within the meaning of 21 U.S.C. 321(g)(2), their intended use in the treatment and cure of arthritis and rheumatism is clear from their newspaper advertising. (R. 58, 59).

The only question before the District Court was whether the labeling of said Tablets failed to bear adequate directions for use in violation of 21 U.S.C. 352(f)(1). This, we submit, was a *question of law,* in view of the admission that the labeling failed to state any disease or condition for which the tablets were recommended.

That this question was recognized by Alberty as one of law is clear from the Exceptions to Libel which it filed. (R. 16-17). In the Exceptions, Alberty contended that the libel was insufficient since the labeling merely failed to include information which the statute did not require. These Exceptions were overruled. (R. 18).

Under the holdings of this Court and a number of others, we believe it settled that the labeling of a drug cannot bear adequate directions for use unless it states the diseases or conditions of the body for which the drug is intended.

In *Colgrove et al. v. United States,* 176 F. (2d) 614, 615 (C.A. 9, 1949), cert. denied 338 U.S. 911 (January 9, 1950), this Court sustained a conviction for criminal contempt where Colgrove, in violation of an injunction issued under the Act of 1938, had shipped drugs interstate with labeling that mentioned only four disease conditions, although his newspaper advertising mentioned eight additional disease conditions. Failure of the defendant to print on the labeling all of the disease conditions mentioned in newspaper advertising, was sufficient basis to hold that the labeling of his drugs did not bear adequate directions for use.[2]

Another significant case on this point is *United States v. Various Quantities . . . "Instant Alberty Food,"* 83 F. Supp. 882 (D.D.C., 1949). Alberty is the claimant in that case also. In its Answer there, Alberty argued as an affirmative defense that the statutory provision regarding adequate directions for use in the labeling "does not require that the labeling of a drug state the diseases or conditions of the body for

[2]In a subsequent proceeding after the defendants put the disease conditions in the labeling, *U.S. v. Colusa Remedy Co.* (S.D. Calif., 8572-WM Civil, June 10, 1949), the District Court issued another injunction permanently restraining the defendants from shipping these drugs interstate with false and misleading therapeutic claims in their labeling.

which the drug when used as directed will be effective, nor does it require that the labeling of a drug state each of the diseases and conditions of the body for which the drug is advertised as a therapeutic treatment." [83 F. Supp. 884].

This affirmative defense was stricken on motion of the Government, the Court observing on page 885:

> "The words, 'adequate directions for use', necessarily relate to some purpose which is to be served by the use, and that purpose must be consistent with the intent of the Act as a whole to protect the public health. For what purpose are drugs used? Obviously, as a remedy for some ailment of the body. *It seems equally obvious that no drug can be said to contain in its labeling adequate directions for its use, unless every ailment of the body for which it is, through any means, held out to the public as an efficacious remedy be listed in the labeling,* together with instructions to the user concerning the quantity and frequency of dosage recommended for each particular ailment. See the following unreported cases, cited in the government's brief: United States v. 150 Pkgs. Bush Mulso Tablets, D.C.E.D.Mo., 83 F. Supp. 875; United States v. 516 Cases, Nue-Ovo, D.C.S.D.Col.
>
> "It may be that compliance with this requirement, thus freeing the shipper from any liability under Section 352(f)(1), would result in the drug being misbranded under Section 352(a) of the Act; and doubtless this is the precise result which was intended in those cases where false and misleading advertising claims are made which are omitted from the labeling." [Emphasis added]

See also:

U. S. v. 150 Packages . . . Bush Mulso Tablets, 83 F. Supp. 875 (E.D. Mo., 1947);

Kleinfeld, *Applicability of the Federal Food, Drug, and Cosmetic Act to Drug Advertising,* Volume 5, Food Drug Cosmetic Law Journal (CCH), page 45, 48-53 (March 1950).

Drugs marketed for ultimate lay use fall into two broad categories: (1) Those which laymen purchase and use without the prescription of a physician, and (2) those which are dispensed to lay users only on the prescription and with the directions of a physician.

By enacting the various subsections comprising Section 502 of the Act [21 U.S.C. 352], Congress clearly sought to develop reasonable and effective safeguards for the public in its use of drugs. The statute is affirmative in its demand that the labeling of a drug intended for lay purchase and use without a physician's prescription bear adequate directions for use, supplying the consumer with information essential to intelligent lay use.[3] In House Report No. 2139, 75th Cong., 3d Session, page 8, the House Committee on Interstate and Foreign Commerce stated:

> "Other provisions of section 502 are designed to require the labeling of drugs and devices *with*

[3]The statute [21 U.S.C. 352(f)] and regulations authorized thereunder [21 Code of Federal Regulations (1949 Ed.), § 1.106(b)] provide that prescription drugs be exempt, on certain conditions, from the requirement that their labeling bear adequate directions for use.

information essential to the consumer. The bill is not intended to restrict in any way the availability of drugs for self-medication. On the contrary, it is intended to make self-medication safer and more effective. For this purpose provisions are included in this section requiring the appropriate labeling of habit-forming drugs, *requiring that labels bear adequate directions for use,* and warnings against probable misuse, and setting up appropriate provisions for deteriorating drugs." [Emphasis added.]

It is difficult to conceive of any information which could be more essential to the consumer regarding a drug which he can purchase without a physician's prescription than a statement or enumeration of the disease conditions for which the drug is to be used. Indeed, without such statement or enumeration no directions for the use of such a drug can be considered adequate under this statute.

The statutory words "adequate directions for use" cannot be construed *in vacuo,* but must be considered in relation to the information they convey to the lay public and to the efficient administration of the statute. Labeling not only serves to inform the ultimate consumer, but also performs the vital function of providing a means of determining compliance with, or violation of, the Act. *McDermott v. Wisconsin,* 228 U.S. 115, 132 (1913); *Arner Co., Inc. v. U.S.,* 142 F. (2d) 730, 734 (C.A. 1, 1944), cert. denied 323 U.S. 730. How can the adequacy of mechanical instructions for the intake or application of a drug be ascertained

for enforcement purposes except in relation to specific diseases, an enumeration of which must form an integral part of the directions for use?

How could it possibly be known whether certain directions for the use of a drug are adequate unless it is known what the drug is to be used for? Unless the statutory requirement of adequate directions for use in the labeling is a futility, the directions in the labeling must refer to the use of the drug in specifically enumerated conditions of disease. Furthermore, where a drug is offered to the public in newspaper advertising for certain disease conditions, it is no imposition upon the legitimate manufacturer to require him to state all of those conditions in the labeling together with directions adequate for its use in those conditions.

The Congressional purpose in requiring that adequate directions for use appear upon the labeling of a drug was to protect the public health. Adequate directions for use are required to enable the purchasing public to practice self-medication safely and effectively by providing information upon the basis of which a person might intelligently dose himself. The complete protection to consumers contemplated by the misbranding provisions of 21 U.S.C. 352(f) is apparent when other requirements of the section are considered. Sec. 352(f) requires that the labeling be completely informative to facilitate intelligent self use. Section 352(a) requires this information to be given truthfully and without misleading implication. Sec-

tion 352(j) requires that the drug be safe for use under the conditions prescribed, recommended or suggested in the labeling. Considering these three requirements together it will be seen that if a manufacturer or shipper is permitted to make claims for his drugs outside of the labeling and is not required to include in the labeling representations specifying all of the diseases or conditions for which he intends his product to be used, paragraphs (f), (a) and (j) of section 352 are reduced to a nullity.

To consider directions such as "Three tablets with a cupful of hot water. Take four times daily. Before meals and on going to bed." (See R. 58) as being adequate, would mean that this product could never be charged under section 352(a) with bearing misleading statements in the labeling—there is no indication on the labeling of the conditions for which these directions are to be followed, nor can the labeling be charged with giving untruthful information when it gives no information at all. Nor could this product be charged with violating section 352(j) if it was dangerous to health when taken as directed for the disease or conditions for which the distributor recommends or suggests it outside of the labeling. The same reasoning applies where the manufacturer or distributor does enumerate some of the symptoms, diseases and conditions in the labeling but fails to enumerate others for which the product is suggested outside of the labeling. The key provision is in section 352(f)(1). That is designed to make the affirmative

requirement of informative labeling. When its requirements are met, the other two provisions are given significant meaning. All of the informative labeling must be true and without misleading implications (352(a)), and the drug must be safe for use when used in the manner directed (352(j)).

In *United States v. Dotterweich,* 320 U.S. 277, 280 (1943), the Supreme Court enunciated a rule of construction for this statute which is particularly appropriate here:

> "The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. *Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of Government and not merely as a collection of English words."* [Emphasis added.]

And in *United States v. Antikamnia Chemical Co.,* 231 U.S. 654, 665, 667 (1914), a case arising under the Food and Drugs Act of 1906, which preceded the instant legislation, the Supreme Court pointed out:

> "The purpose of the act is to secure the purity of foods and drugs *and to inform purchasers of what they are buying.* Its provisions are directed to that purpose and must be construed to effect it."
>
> * * * * * * *
>
> *"The purpose of the law is the ever insistent consideration in its interpretation."* [Emphasis added.]

See also pronouncements of this Court in *Research Laboratories, Inc. v. United States,* 167 F. (2d) 410, 421 (C.A. 9, 1948), cert. denied 335 U.S. 843 (1948); *Pasadena Research Laboratories v. United States,* 169 F. (2d) 375, 379 (C.A. 9, 1948), cert. denied 335 U.S. 853 (1948).

As we have shown, one of the purposes of Section 502(f)(1) [21 U.S.C. 352(f)(1)] is to assure that lay use of a drug in self-medication will be safe in those conditions or diseases for which the drug is offered to the public. If this section were to be interpreted as authorizing the omission from the labeling of the conditions of disease for which the drug is offered, it would result in the creation of a serious defect in the statute permitting the very mischief intended to be redressed. Any worthless drug could then use the channels of interstate commerce with impunity, not being required to come out in the open with therapeutic representations in the labeling which would of necessity be false and misleading.

This construction of the law works no hardship on honest enterprise. As recognized by the District Court for the District of Columbia in the *Instant Alberty Food* case, *supra,* 83 F. Supp. at page 885, the omission of disease conditions from the labeling is the last resort of those who know that the mention of the disease conditions in the labeling will subject them to the charge that their drugs are misbranded under 21 U.S.C. 352(a) by reason of false and misleading therapeutic claims. If the disease conditions

are mentioned, the labeling is false and misleading. If the disease conditions are not mentioned, the labeling does not bear adequate directions for use. This is a sort of legal squeeze play by which the Government hopes to eliminate worthless panaceas from the channels of commerce.

Ri-Co Tablets are typical of the type of drug that cannot come out into the open with therapeutic claims in its labeling. As we have shown, an earlier shipment of Ri-Co Tablets with therapeutic claims in its labeling for arthritis, rheumatism, and rheumatic gout, was condemned together with a number of other Alberty products in a default decree. [Drugs and Devices Notice of Judgment 2057]. The unrefuted medical affidavits in the record substantiate the Government's contention as to the worthlessness of these Tablets. (R. 61-71). While the District Court did not find it necessary to determine whether Ri-Co Tablets are worthless, it stated: "There is no showing of any loss to humanity or posterity if the Ri-Co Tablets under seizure are destroyed." (R. 28 and 50).

Alberty's Opening Brief raises a number of points that merit little if any consideration. Thus on page 15, the argument is made that the "label" of a drug is so small that it cannot contain all the information which the Government contends the "labe*ling*" should contain; but if Alberty put "adequate directions for use" in accompanying literature which constitutes "labeling" the Government would contend that those directions must be on the "label". The

speciousness of this argument is shown by the fact that no such contention was made by the Government in Drugs and Devices Notice of Judgment 2057 or in the pending injunction suit against Alberty in the Southern District of California. In addition, the future action of the Government with respect to Alberty's labeling is entirely speculative. The requirements of the Act in this case cannot be evaded by conjuring up possibilities of other suits at some remote time.

On page 16, appellant quotes a sentence from a statement of Mr. Walter G. Campbell, formerly Chief of the Food and Drug Administration, as evidence that the Administration itself felt that it was optional with the manufacturer whether disease conditions should be stated in the labeling. The implication is that the section being discussed was a forerunner of the present Section 352(f)(1). The quotation does not bear out claimant's conclusion at all. The very first paragraph of Mr. Campbell's testimony makes clear that his comments were concerned with Section 8*(a)* of the bill under consideration. As appellant recognizes, this proposed section dealt with the requirement that once a disease name was mentioned, the labeling must also contain information as to whether the product was a cure or palliative. But this in no way involves adequate directions for use. There was, in fact, in the same draft, an entirely separate section devoted to adequate directions, namely, 8*(e)*, which read that a drug shall be deemed to be misbranded

> "if its labeling fails to bear plainly and conspicuously (1) complete and explicit directions for use * * *"

Thus it was 8(e), not 8(a) that was the predecessor of Section 352(f)(1). The section of the bill to which Mr. Campbell's comments referred does not appear in the bill as enacted. It is obviously a distortion of his testimony to imply that remarks made with respect to this section have any bearing on the interpretation of Section 352(f)(1), an entirely unrelated section that became part of the law.

On Page 17 of Alberty's opening brief, the customary charge of unconstitutionality is hurled at the Government's construction of the Act. The statute, it seems, is vague and uncertain. In an analogous case, *U.S. v. 95 Barrels . . . Vinegar,* 265 U.S. 438, 442-3 (1924), the Supreme Court said:

> "The statute is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. *It is not difficult to choose statements, designs, and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act.*" [Emphasis added].

So in the instant statutory provision, it is not difficult to write adequate directions for use for drugs which may be safely and efficaciously used by the layman without a physician's prescription. There is nothing abstruse or mystical about this requirement. It is only necessary that the labeling of such a drug state (1) all of the diseases or conditions of the body for which it is intended, (2) how much to be taken, (3) how often to be taken, (4) how long to be taken, (5) at what times to be taken, (6) the route or method of administration or application, (7) how to prepare the drug for use (shake well, etc.), and any other information that would be necessary for the safe, intelligent, and effective use of the particular drug. [21 C.F.R. § 1.106(a)(1)-(7)]. Many such drugs are readily available for self-medication in the drug stores today.

We admit, however, that it is difficult to write "adequate directions for use" for a *worthless* drug without making false and misleading therapeutic claims. We doubt that this would support a charge of unconstitutionality. Alberty's difficulty lies not in failing to understand the statute but in trying to circumvent it.

On pages 20-22, the charge is made that the Government in this proceeding under the Federal Food, Drug, and Cosmetic Act seeks to regulate advertising. This is not true. The Government is only seeking full compliance with the labeling requirements of the Federal Food, Drug, and Cosmetic Act. If as an indi-

rect result of such compliance, a manufacturer must temper his advertising claims, that is no reason why the Government should relax its vigilance with respect to data required in the labeling.

For the foregoing reasons, we submit that there was no genuine *issue of fact* before the District Court. The only question before the Court was one of *law* which had already been decided in favor of the Government when the District Court overruled the Exceptions to Libel. (R. 18). Actually counsel for Alberty suggested to the District Court in oral argument that he would consent to a decree of condemnation if the Court would permit relabeling of the Ri-Co Tablets pursuant to a decision of the Federal Trade Commission. (R. 44). The major consideration in the District Court was whether the Court should permit relabeling of the Tablets under 21 U.S.C. 334(d), after entry of a decree of condemnation. (R. 44-53). The District Court's ruling on this point is not questioned on appeal. [Appellant's Opening Brief, page 6].

We further submit that the District Court did not err in holding that the labeling of a drug does not bear adequate directions for use under 21 U.S.C. 352(f)(1) unless, among other things, it states the diseases or conditions of the body for which the drug is offered to the public.

D. THE SUMMARY JUDGMENT PROCEDURE AUTHORIZED BY CIVIL RULE 56 WAS PROPERLY INVOKED BY THE DISTRICT COURT.

The pertinent portions of the summary judgment procedure authorized by Civil Rule 56 appear in subsections (a) and (c):

> *Civil Rule 56(a)*
>
> "A party seeking to recover upon a claim, counterclaim, or cross-claim or to obtain a declaratory judgment may, at any time after the expiration of 20 days from the commencement of the action * * * move with or without supporting affidavits for a summary judgment in his favor upon all or any part thereof."

> *Civil Rule 56(c)*
>
> "* * * The adverse party prior to the day of hearing may serve opposing affidavits. The judgment sought shall be rendered forthwith if the pleadings, depositions, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law * * *"

On page 9 of Appellant's Opening Brief, a devious argument is made that the United States, in a condemnation proceeding, is not "a party seeking to recover upon a claim, etc." within the meaning of Civil Rule 56(a). The answer to this assertion is simple. In the Notes of Advisory Committee on Rules, the very first sentence relating to this Rule reads:

> "This rule is applicable to *all* actions, including those against the United States or an officer or agency thereof." [Emphasis added].

On page 11 of its opening brief, Appellant cites two decisions of this Court apparently to support its argument that a summary judgment was improper in this case:

> *Gifford v. Travelers Protective Ass'n of America,* 153 F. (2d) 209 (C.A. 9, 1946);
>
> *Koepke v. Fontecchio,* 177 F. (2d) 125 (C.A. 9, 1949).

Actually, in both of these cases the summary judgment entered by the District Court was *upheld* by this Court based upon pronouncements that accord with our position.

The opinion of this Court in the *Koepke* case was written by Judge Gardner, Chief Judge of the Eighth Circuit, sitting by special designation. In another very recent opinion, *Hurd v. Sheffield Steel Corp.,* 181 F. (2d) 269 (C.A. 8, April 25, 1950), written by Judge Gardner sitting in the Eighth Circuit, there is a concise review of the significant principles that relate to summary judgment. On page 271, the Judge stated:

> "The proceeding on motion for summary judgment is not a trial but in the nature of an inquiry in advance of trial for the purpose of determining whether there is a genuine issue of fact. Rule 56, Federal Rules of Civil Procedure, 28 U.S.C.A., contemplates prompt disposition of an

> action where there is in fact no genuine issue, thus avoiding the necessity of a futile trial. Either party may move for summary judgment—the plaintiff at any time after the answer has been served, and the defendant at any time after claim has been asserted against him. The burden of proof is on the moving party and the rule [56(e)] requires that affidavits supporting or opposing a motion for summary judgment shall be made on personal knowledge and set forth such facts as would be admissible in evidence and which show that the affiant is competent to testify to the facts recited in the affidavit. If it appears from the pleadings, affidavits, admissions, or depositions that there is no genuine issue as to any material fact and that the issue is one of law, then if the law so warrants a summary judgment should be entered. The question of the sufficiency of the evidence raises an issue of law and if, under the facts, the court would be required to direct a verdict for the moving party, then a summary judgment should be granted * * * [Citing cases including *Gifford v. Travelers Protective Ass'n, supra,* 153 F. (2d) 209 (C.A. 9, 1946).]."

We submit that these principles, applied to the instant case, demonstrate the correctness of the District Court's judgment. As we have shown, there was no genuine issue of fact before the Court. That the article then under seizure was a drug, that it had moved interstate, that its labeling did not state any disease or condition of the body for which it was offered—*all of these facts were conceded.* Since, as a matter of

law, the labeling of a drug fails to bear adequate directions for use, in violation of 21 U.S.C. 352(f)(1), unless it does declare the diseases or conditions of the body for which the drug is offered to the public, we submit that there was no genuine issue of fact and that the Government would have been entitled to a directed verdict had the case gone to trial before a jury.

We submit that this case was a most appropriate one in which to invoke the summary judgment procedure.

VII.

CONCLUSION.

The situation disclosed in this case is typical of what is frequently found by the Government in its effort to require compliance with the Federal Food, Drug, and Cosmetic Act. All that Act requires is simple honesty and fair dealing on the part of a drug proprietor.

Despite maximum vigilance and repeated enforcement actions, some of these drugs, including Ri-Co and other Alberty products, remain on the market for years, their proprietors constantly shifting ground, modifying their labeling representations and promotional methods, and always invoking distorted constitutional safeguards for their asserted right to defraud the American public.

Since the Ri-Co Tablets here involved were destroyed by reason of Alberty's negligence in protecting its right of appeal, it is submitted that this Court is without jurisdiction to entertain this appeal, and should dispose of the case simply by dismissing the appeal.

If the Court does have jurisdiction to consider the appeal, we submit that no error was committed in the proceedings below, and that the judgment of the District Court should in all respects be affirmed.

Dated, San Francisco, California,
July 25, 1950.

Respectfully submitted,

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